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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,813

09/11/2006

Barry Allen

ETF-0040

4455

23413 7590 07/01/2008  
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EXAMINER

NATARAJAN, MEERA

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

07/01/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/567,813	<b>Applicant(s)</b> ALLEN ET AL.	
	<b>Examiner</b> MEERA NATARAJAN	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04/03/2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-43 is/are pending in the application.
- 4a) Of the above claim(s) 24, 28, 29 and 34-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23, 25-27 and 30-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/09/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I, Claims 21-27 and 30-33 and species election Bi213 in the reply filed on 04/03/2008 is acknowledged. The traversal is on the ground(s) that Allen nor Denton taken alone or in combination teach usage of C595 in **radio**-immunotherapy as recited in the Claims, especially in a radioconjugate where it is bound to an alpha-emitter. This is not found persuasive because Allen et al. discloses alpha-immunoconjugates and alpha-protein conjugate, using the alpha-emitting **radionuclides** Bi-213 chelated to targeting antibodies. Denton et al. disclose a monoclonal C595 antibody, although it is a single chain antibody, it still reads on the claim. Therefore there would be motivation to combine the two compositions for increased target specificity for cancer therapy as disclosed in Allen et al. The requirement is still deemed proper and is therefore made FINAL.
2. Claims 28, 29, and 34-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/03/2008.
3. Claim 24 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/03/2008.
4. Claims 21-23, 25-27 and 30-33 will be examined on the merits.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 21-23, 25-27 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. (J of Nuclear Medicine, Vol. 42, pp. 726-732, 2001) in view of Allen et al. (Critical Reviews in Onc./Hematology, Vol. 39, pp.139-146, 2001).

8. The Claims are drawn to a radioimmunoconjugate and radiopharmaceutical comprising an alpha-emitting radionuclide (Bi-213) bound to a monoclonal antibody, C595.

9. Murray et al. teach a radioimmunoconjugate comprising the c595 antibody labeled with a dual  $\beta$ - and  $\gamma$ - emitting radionuclide to target bladder tumors (see Abstract). Murray et al. does not teach an antibody conjugated to an alpha-emitting radionuclide (Bi-213). This deficiency is made up for by Allen et al.

Art Unit: 1643

10. Allen et al. teach alpha-immunoconjugates and alpha-protein conjugates, using the alpha-emitting radionuclide Bi-213 chelated to the targeting monoclonal antibodies (see p. 140, right column, lines 3-6). The chelating agents used were cDTPAa and CHX-A (see section 3.1, p. 142). These conjugates were found to be highly stable, specific and cytotoxic in vitro (see Abstract).

11. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to make a radioimmunoconjugate comprising the C595 monoclonal antibody and the alpha-emitting radionuclide Bi-213 based on the teachings of Allen et al. and Murray et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Allen et al. and Murray et al. because Murray et al. teach radioimmunoconjugates comprising radionuclides and the C595 monoclonal antibody and Allen et al. teach alpha-emitting radioimmunoconjugates are highly stable, specific and cytotoxic.

12. The claimed product can be viewed as a composition comprising a combination of ingredients known in the art to be useful for the same purpose, i.e. In re Kerkhoven analysis (In re Kerkhoven, 626, F.2s 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)). The court held that it is obvious to combine two compositions, in order to form a third composition, when each of the two compositions is taught by the prior art to be useful for the same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (MPEP 2144.06). Both Allen et al. and Murray et al. teach compositions for the use of cancer therapy.

***Conclusion***

13. Claims 21-23, 25-27 and 30-33 are rejected.
14. No claim is allowed.
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/567,813  
Art Unit: 1643

Page 6

/Larry R. Helms/  
Supervisory Patent Examiner, Art Unit 1643